

## **REMARKS**

### **Status of the Claims**

Claims 90-96, 98-126, 128-167, and 173-215 are currently pending in the subject application. By this amendment, Claims 90, 120 and 167 have been amended without prejudice or disclaimer.

Claim 90 has been amended to recite that the metered sample is formed in the holding chamber. Claims 90 and 167 have been amended to recite that the metered sample is moved from the holding chamber to the analysis location by pumping through the overflow chamber as suggested in the July 3, 2009 Examiner interview. Claim 120 has been amended for clarity. No new matter has been added.

### **July 3, 2009 Examiner Interview**

Applicants would like to thank Examiner Alexander for the personal interview conducted on July 3, 2009. In compliance with M.P.E.P. § 713.04, the substance of that interview is reflected in the July 7, 2009 Interview Summary and in the following remarks.

In the interview, the Office proposed a modification to Claim 90 to recite that the metered sample is moved from the holding chamber to the analysis location by “pumping through the overflow chamber.” This Amendment adopts that proposal. Applicants note with appreciation the Examiner’s acknowledgment that the apparatus claims are clearly directed to structure that appears to define over Sheppard et al.

### **Rejections Under 35 U.S.C. §112, Second Paragraph**

Claims 90-96, 98-126, 128-167, 173-174 and 182 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully traverse these rejections.

Concerning Claims 90, the Office has asserted that it is not clear how the sample is metered in the overflow chamber. Claim 90 has been amended to indicate that the metered sample is formed in the holding chamber by directing excess fluid to the overflow chamber; the

sample is not metered in the overflow chamber. Accordingly, Applicants request the withdrawal of the rejection of Claim 90.

The Office also asserts that it is not clear how the metered sample is mixed with the reagent or how the reagent is moved into the analysis location. Applicants respectfully disagree and direct the Office to pages 19 and 21-22, FIG. 2 and FIGS. 6A-C of the as-filed application, which fully describe some exemplary embodiments of how the reagent may be mixed with the sample and moved over the sensor in the analysis location. The Office also asserts that it is not clear what steps are performed by the claimed “closable sample entry port.” As discussed in the July 3, 2009 Examiner Interview, the exact form of the closable sample entry port may vary widely, but one exemplary sample entry port is shown in FIG. 2 and fully described in the paragraph bridging pages 14 and 15 of the as-filed application. Applicants assert that the use of the closable sample entry port would be well within the skill in the art in view of this description. For the foregoing reasons, the withdrawal of this rejection is respectfully requested.

Concerning Claim 98, the Office has asserted that it is not clear how the sample is forced into the overflow chamber by closure of the sample entry port. The Office has incorrectly assumed that the pump changes the pressure in the system to force the sample into the overflow chamber. As described on pages 17-18 of the as-filed application, as the closure mechanism is shut, pressure may be exerted by the closure mechanism on the fluid in the holding chamber causing excess fluid to be pushed through an orifice and into the overflow chamber. The pump then pumps through the overflow chamber (and around the excess fluid contained therein) to force the metered sample from the holding chamber. Applicants respectfully assert that from this description, the manner in which the closure can effect movement of excess fluid into the overflow chamber would be readily appreciated by those skilled in the art. The withdrawal of this rejection is accordingly requested.

Concerning Claims 101 and 182, the Office has asserted that the recited “pre-sensor chamber” is unclear. These claims indicate, however, that the pre-sensor chamber is “located between the holding chamber and the analysis location.” In addition, the specification shows and describes the pre-sensor chamber in FIG. 4 and at page 17 as a chamber between the holding

chamber and the analysis location. With reference to FIG. 2, the subject application further indicates that “a metered sample is forced from the sample holding chamber 20 through the pre-sensor channel 24 into the analysis location 31 as the plunger in the analyzer compresses the cartridge air bladder 36 and forces air through the air pipe 18 into the overflow chamber 16 and through the orifice (48 in FIG. 5).” (Specification at p. 18.) Accordingly, from a process standpoint, Applicants submit that those skilled in the art would appreciate that the metered sample formed in the holding chamber passes through the pre-analysis chamber in order to arrive at the analysis location. In view of this description, Applicants submit that Claims 101 and 182 are sufficiently clear and request the withdrawal of these rejections.

Concerning Claim 115, the Office has indicated that it is not clear how the overflow chamber is treated to impart high energy surface to the interior. The Office has assumed that pressure is intended. Applicants respectfully do not understand the basis for this rejection, and refer the Examiner to page 15 of the subject application, which recites:

The sample is deposited in the cartridge through the sample entry port 12 in FIG. 2 and shown in cross-section as 12 in FIG. 3. The opening is designed so that capillary forces will draw a hanging drop touched to the orifice of the port into the cartridge and toward the sample holding chamber. The action is a result of the geometry and high surface energy of the plastic conduit. A high surface energy is achieved with a corona treatment or equivalent treatment, such as an ion-plasma treatment, before cartridge assembly.

In view of this description, Applicants submit that it would be clear to those skilled in the art how the overflow chamber may be treated to impart high energy surface characteristics, and Claim 115 is sufficiently definite. The withdrawal of this rejection is accordingly requested.

Concerning Claim 120, the Office has asserted that it is not clear what method steps are intended by “a lower interior surface-to-volume ratio” because these appear to be structural limitations. Although it is a common PTO practice to disregard process limitations when examining composition or apparatus claims, Applicants submit that it is wholly improper to disregard structural limitations when examining process claims since the process limitations are tied to the manipulation of the structural elements. Accordingly, the structural limitations in Claim 120 are proper, sufficiently definite and must be considered. In addition, the Examiner

has asserted that the term “lower” is unclear. Although Applicants disagree, to expedite prosecution Applicants have amended Claim 120 to specify that the interior surface-to-volume ratio of the holding chamber is less than the interior surface-to-volume ratio of the overflow chamber. Withdrawal of this rejection is respectfully requested.

Claim 126 has been rejected on the basis that it allegedly is unclear what products are intended. Applicants disagree and point out that the blood clotting process is well understood to occur as fibrin strands, which are generated by the action of thrombin on the plasma protein fibrinogen, cross-link to form a three dimensional structure. Conversion of fibrinogen occurs as the final step in a series of enzyme reactions in which sequential coagulation enzymes, or factors, are activated. This process is described with reference to FIG. 1 at page 13 of the subject application and in original Claim 44 of the parent application Serial No. 09/712,209. The withdrawal of this rejection is accordingly requested.

Rejection Under 35 U.S.C. §102(e)

Claims 90-96, 98-126, 128-136, 144-146, 148, 150-158, 167, 173-203 and 212-215 stand rejected under 35 U.S.C. §102(e) as being anticipated by Sheppard et al. (USP 6,143,247). Applicants respectfully traverse this rejection.

As discussed in the July 3, 2009 Examiner Interview and in previous responses, the claimed invention relates to cartridges and methods for using cartridges having a highly unique and counterintuitive approach to forming metered samples. In the claimed cartridges and methods, a fluid sample is introduced into a holding chamber. A metered sample is formed in the holding chamber by retaining any excess fluid in an overflow chamber, which is oriented between a pump and the holding chamber. Once the metered sample has been formed, a pump moves the metered sample from the holding chamber to an analysis location ***by pumping through the overflow chamber***. This approach is wholly counterintuitive since pumping through the overflow chamber (and through any overflow fluid contained therein) would be thought to be detrimental as excess fluid would be expected to backflow out of the overflow chamber to undesirably mix with the metered sample. As indicated in the subject application, however, “[t]he high surface area to volume ratio of [the overflow chamber] encourages sample shear so

that the air pushes a path through the excess sample leaving the excess sample on the walls of the overflow chamber.” (Specification at page 18.) Thus, the act of pumping through an overflow chamber to move a metered sample that is contained in a holding chamber is a highly novel and unique approach to forming a metered sample.

Applicants submit that none of the references of record disclose or suggest a cartridge in which an overflow chamber is disposed between a pump and a holding chamber, and no reference of record discloses a process in which a pump moves the metered sample from the holding chamber to an analysis location *by pumping through the overflow chamber* as presently claimed. As a result, Applicants submit that all of the pending claims are in condition for allowance over the references of record.

Sheppard et al., for example, is directed to methods and devices for detecting and quantifying particular matter suspended in a fluid. (Sheppard et al. Abstract.) In operation, the Sheppard et al. device is rotated to provide centripetal force to effect fluid flow on the device. (Sheppard et al. at Col. 13, lines 10-15.) In contrast to the claimed invention, the device shown in Sheppard et al. FIG. 2 has an overflow chamber 23 that *is entirely separate* from the detection chamber 24. Moreover, as indicated above, Sheppard et al. relies upon centripetal force to move fluids and does not use a pump.<sup>1</sup> Accordingly, Sheppard et al. is completely silent concerning the required structure and process limitations contained in the pending claims.

Simply put, nowhere does Sheppard et al. disclose or suggest *an overflow chamber disposed between a pump and a holding chamber* as required by independent Claims 90, 167 and 175 and the claims depending therefrom. Similarly, Sheppard et al. fails to teach or suggest a step of moving a metered sample from a holding chamber to an analysis location *by pumping through an overflow chamber* as required by Claims 90, 167, 173 and 175, and the claims depending therefrom. For at least the foregoing reasons, Applicants assert that pending Claims

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<sup>1</sup> Although Sheppard mentions at Col. 13, lines 34-45, that fluid movement may be achieved by “pumping,” nowhere does Sheppard enable the use of a pump or suggest that required orientation and structure of the holding chamber, overflow chamber and pump that are recited in the pending claims. Accordingly, Sheppard cannot and does not anticipate any of the pending claims.

90-96, 98-126, 128-136, 144-146, 148, 150-158, 167, 173-203 and 212-215 are patentable over Sheppard et al.

Rejection Under 35 U.S.C. §103(a)

Claims 137-143, 147,<sup>2</sup> 149, 159-166 and 204-211 stand rejected under 35 USC §103(a) as being unpatentable over Sheppard et al. in view of Zelin et al. (USP 5,124,661). Applicants traverse this rejection.

As indicated above, Sheppard et al. fails to teach or suggest the claimed orientation of the holding chamber, the overflow chamber and the pump. In addition, Sheppard et al. fails to teach a step of moving a metered sample from a holding chamber to an analysis location by pumping through an overflow chamber. These deficiencies of Sheppard et al. are not remedied by Zelin et al. For at least the foregoing reasons, Applicants respectfully assert that a prima facie case of obviousness has not been established, and the withdrawal of this rejection is respectfully requested.

Conclusion

For the foregoing reasons, Applicants earnestly submit that the pending claims are in condition for allowance over the references of record, and a notice thereof is respectfully requested.

Should the Examiner have any questions regarding this response or the application in general, the Examiner is urged to contact the Applicants' attorney, Justin L. Krieger, by telephone at (202) 625-3858. All correspondence should continue to be directed to the address given below.

Respectfully submitted,

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<sup>2</sup> As corrected in the April 16, 2009 Examiner Interview Summary.